REMARKS/ARGUMENTS

Applicants note the withdrawal of the rejections of the claims under 35 U.S.C. §102(b) as being anticipated by Bontempo *et al.* (EP 0 284 249), Hwang-Felgner *et al.* (U.S. Patent No. 5,151,265), and Olefsky *et al.* (WO 96/40894).

Claims 11, 12, 35-37, and 41-44 have been canceled in view of amendments to claim 1 and the Examiner's indication that claims 11 and 12 would be allowable if rewritten in independent form. Claim 1 has been amended to recite a Markush group of pharmaceutically active agents. Support for this list of agents resides in the specification, for example, at page 8, lines 3-14. The specification has been amended in the paragraph at page 8, lines 3-14, to correct obvious typographical errors. No new matter is added by way of these amendments to the claims and specification.

Responsive to the Examiner's indication that claim 11 and 12 are allowable if rewritten in independent form, Applicants have canceled these claims and rewritten them as new independent claim 45 and new dependent claim 46, respectively. New claims 47-52 are also presented. New claim 47 recites a sterile injectable non-sustained-release pharmaceutical composition comprising a pharmaceutically active agent and a buffer that consists substantially of succinate at a concentration of 7 mM to 45 mM and a counterion. Support for recitation of this composition resides in original claim 1, and in the specification, for example at pages 17 through 18, where the types of pharmaceutical formulations are discussed, and particularly at page 18, lines 2-23, where sustained-release pharmaceutical compositions of the invention are set forth as distinct embodiments of the invention. New claims 48-52 recite specific embodiments of this composition; support for these claims resides in the specification and in the original claims. No new matter is added by way of presentation of these new claims.

Claims 1-10, 13, 14, 21-34, 38-40, and 45-60 are now pending in the application. The Examiner's comments in the Office Action are addressed below in the order set forth therein.

The Provisional Obviousness-Type Double-Patenting Rejection

Claims 1-8, 13, 14, and 35-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 9, 12, 13, 36-40, 45, 47, and 48 of copending application US 2002/0172661 A1 (Application No.

10/035,397). As noted by the Examiner, a timely filed terminal disclaimer in compliance with 37 C.F.R. §1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR §1.130(b).

Copending Application No. 10/035,397 and the present application are commonly owned by virtue of assignments recorded at the U.S. Patent and Trademark Office. The copending application is still in the process of examination. Thus, it is not yet known which of these applications will be the first to be allowed for issuance as a patent. Should the copending application be the first to be in condition for allowance, Applicants will, upon notification to this effect, either argue the double-patenting rejection or timely file a terminal disclaimer in the present application.

The Rejection of the Claims Under 35 U.S.C. §102 Should Be Withdrawn

Claims 1-10, 13, 14, and 35-40 are rejected under 35 U.S.C. §102(b) as being anticipated by Profitt *et al.*, EP 0 317 120 (May 1989). Claims 35-37 have been canceled. This rejection is respectfully traversed as applied to the remaining amended claims.

Profitt *et al.* teach the dry powder of a lipid solution containing amphotericin B-DSPG complex hydrated in an aqueous buffer of 9% (w/v) lactose and 10 mM sodium succinate at pH 5.5. Profitt *et al.* do not teach Applicants' claimed invention.

Claims 1-10, 13, 14, and 38-40 are directed to a sterile injectable pharmaceutical composition comprising a pharmaceutically active agent and a buffer, where the buffer consists substantially of succinate at a concentration of 7 mM to 45 mM and a counterion, and the pharmaceutically active agent is selected from a group of agents that does not include amphotericin B-DSPG. The Profitt *et al.* reference does not teach the use of succinate buffer to formulate the pharmaceutically active agents recited in the pending claims. As such, this reference does not anticipate the presently claimed compositions, and this rejection of the claims should be withdrawn.

Furthermore, the newly presented claims are directed to pharmaceutical compositions comprising IGF-I or variant thereof (claims 45 and 46) or to non-sustained-release pharmaceutical compositions (claims 47-52). Applicants respectfully submit that Profitt *et al.* do

not teach these compositions. Therefore, this rejection should not be applied to the newly presented claims.

Claims 1-5, 9, 10, 13, and 35-40 are rejected under 35 U.S.C. §102(b) as being anticipated by Cleland *et al.*, US 2002/0004481 (filed June 11, 1998). This rejection is respectfully traversed.

Cleland *et al.* teach a controlled-release microencapsulated nerve growth factor (NGF) formulation. The formulation optionally comprises a buffering agent, of which succinate is generically disclosed as a member of the group of buffering agents that can be used at a concentration of about 2 mM to about 100 mM. Cleland *et al.* do not teach Applicants' claimed invention.

Claims 1-5, 9, 10, 13, and 35-40 are directed to a sterile injectable pharmaceutical composition comprising a pharmaceutically active agent and a buffer, where the buffer consists substantially of succinate at a concentration of 7 mM to 45 mM and a counterion, and the pharmaceutically active agent is selected from a group of agents that does not include NGF. The Cleland *et al.* reference does not teach the use of succinate buffer to formulate the pharmaceutically active agents recited in the pending claims. As such, this reference does not anticipate the presently claimed compositions, and this rejection of the claims should be withdrawn.

Furthermore, the newly presented claims are directed to pharmaceutical compositions comprising IGF-I or variant thereof (claims 45 and 46), or to non-sustained-release pharmaceutical compositions (claims 47-52). Applicants respectfully submit that Cleland *et al.* do not teach these compositions. Therefore, this rejection should not be applied to the newly presented claims.

CONCLUSION

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. §102 are overcome, and the obviousness-type double-patenting rejection is moot absent an indication that copending U.S. Application No. 10/035,397 has been granted a notice of allowance prior to such grant in the present application. Accordingly, Applicants submit that this application is

now in condition for allowance. Early notice to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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Lynda-Jo Pixley